4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1874]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Perceptions of Prescription Drug Products with Medication Tracking Capabilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The title of this information collection is "Perceptions of Prescription Drug Products with Medication Tracking Capabilities." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Perceptions of Prescription Drug Products with Medication Tracking Capabilities

OMB Control Number 0910-NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated so that patients and health care providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to

develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our home page at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research, which includes links to the latest *Federal Register* notices and peer-reviewed publications produced by our office.

Patient non-adherence to medication regimens is a well-known challenge in health care. The World Health Organization defines adherence as the extent to which a person's behavior--taking medication, following a diet, and/or executing lifestyle changes--corresponds with agreed recommendations from a health care provider (Ref. 1). It is estimated that only half of all patients with chronic health conditions take their medications as prescribed (Ref. 2), leading to as many as 100,000 preventable deaths and $100 billion in additional medical costs every year (Ref. 3). Numerous solutions have been tried to improve adherence, including resource-intensive approaches such as directly observed therapy, which entails a trained observer watching as the patient takes their medications (Ref. 4), and technology-supported tools for patients (e.g., smartphone apps) (Ref. 5). As attention to the public health issue of medication adherence has grown, OPDP has noted a corresponding increase in the number of claims and presentations in prescription drug promotion that focus, either directly or through implication, on a product's potential to improve adherence to treatment regimens. Many of these presentations include information about options and capabilities available to help patients track their medication usage.

One avenue that prescription drug sponsors have begun exploring to track medication use includes the development of software that is disseminated by or on behalf of the drug sponsor and accompanies one or more of the sponsor's prescription drugs. This software is called prescription drug use-related software.[1] Studies exploring drug products with prescription drug

[1] In 2018, FDA established a public docket to solicit public comment on a proposed framework for regulating software applications disseminated by or on behalf of drug sponsors for use with one or more of their prescription drug products. See https://www.federalregister.gov/documents/2018/11/20/2018-25206/prescription-drug-use-related-software-establishment-of-a-public-docket-request-for-comments.

use-related software have been conducted with medications to treat an array of chronic disorders, including psychiatric disorders (Ref. 6), uncontrolled type 2 diabetes (Ref. 7), end-stage renal disease requiring transplants (Ref. 8), and opioid use among patients with acute fractures (Ref. 9).

In recent years, new technologies that capture data on medication-taking behavior and drug administration have been employed. The SureClick 2.0 autoinjector for the prescription medication ENBREL, for example, has Bluetooth built into the white cap that covers the needle. The autoinjector records initial removal of the cap and can send this data via Bluetooth to a paired smartphone using a mobile app (Ref. 10). Technology can also now support the use of ingestible sensors embedded in pills that will emit a weak signal to a receiver (patch or lanyard) worn by the patient after the pill has been swallowed (Ref. 11). These data can then be transmitted to a paired mobile device and viewed by the patient through a smartphone app (Ref. 12). Whether these new technologies will have an impact on adherence is currently unknown.

Very little is known about patient and health care provider perceptions of products that track medication use or that work in tandem with software to track medication use, with most commentaries having been largely theoretical (Refs. 13 and 14). The focus of the present study is to explore patient and health care provider perceptions of a fictitious prescription drug product that is accompanied by software that is intended to track medication use.

We have the following specific questions:

Research questions:

1. When prescription drug promotional communications include claims about a product's ability to track medication use, do these claims influence perceptions about the product's risks and/or benefits (including its effect on medication adherence)?

2. If the promotional claims about the product's ability to track medication use are accompanied by a disclosure that describes what is known about the effect of medication tracking on

medication adherence, does this have an influence on perceptions of the product's risks and/or benefits (including its effect on medication adherence)?

To complete this research, we propose the design in table 1, which varies based on:

- Whether the fictitious prescription drug product includes technology that tracks medication use;
- Whether the prescription drug promotional communication includes a disclosure describing what is known about the tracking technology's effect on medication adherence; and
- What the disclosure communicates about the tracking technology's effect on medication adherence (positive effect shown, no effect shown, or unknown effect).

Table 1--Proposed One-Way, Five-Level Design (1 × 5)

Experimental Condition	Claims About Existence of Medication Tracking Technology	Disclosure About Technology's Effect on Adherence	Content of Disclosure
1. Drug	No	No	---
2. Drug + medication tracking technology	Yes	No	---
3. Drug + medication tracking technology + no adherence data collected	Yes	Yes	No data are available on the technology's effect on adherence
4. Drug + medication tracking technology + data show no effect on adherence	Yes	Yes	Data show the technology has no effect on adherence
5. Drug + medication tracking technology + data show a positive effect on adherence	Yes	Yes	Data show the technology has a positive effect on adherence

Note: Condition 5 is the only condition in which an adherence benefit has been demonstrated for the fictitious product. The evidence required to support a medication adherence claim is not the focus of this study, and the evidence will not be described in the disclosure.

Condition 2 is a control because the drug product does include medication tracking technology, but the promotional communication does not include a disclosure about the technology's effect on medication adherence. Condition 1 is a true control because the drug product does not include medication tracking technology. Comparisons between conditions 1 and 2 will show us the baseline of this issue, i.e., will indicate whether the fact that the drug product contains a tracking technology will alter perceptions of risks and benefits (including adherence).

We will conduct pretests with 50 consumers who self-identify as having been diagnosed with diabetes and 50 primary care physicians who treat diabetes (both obtained from a web-based research vendor) to ensure that the questionnaire programming works as expected. For the

main study, we will then recruit 350 consumers who self-identify as having been diagnosed with diabetes and 350 primary care physicians who treat diabetes. Each participant will see one of five versions of a consumer webpage for a fictitious prescription diabetes treatment, as reflected in table 1. They will answer a questionnaire designed to take no more than 20 minutes regarding their perception of the product's benefits, risks, and effect on adherence.

In the *Federal Register* of September 23, 2022 (87 FR 58103), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one submission that was not PRA-related (*regulations.gov tracking number lar-vv69-9wok*).

FDA estimates the burden of this collection of information as follows:

Table 2.--Estimated Annual Reporting Burden[1, 2]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
Screener Consumers	680	1	680	.08 (5 minutes)	54.4
Screener Primary Care Physicians	680	1	680	.08 (5 minutes)	54.4
Pretest Consumers	50	1	50	.33 (20 minutes)	16.5
Pretest Primary Care Physicians	50	1	50	.33 (20 minutes)	16.5
Main Study Consumers	350	1	350	.33 (20 minutes)	115.5
Main Study Primary Care Physicians	350	1	350	.33 (20 minutes)	115.5
Total					372.8

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at

the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*1. World Health Organization, "Adherence to Long-Term Therapies: Evidence for Action," p. 3, 2003, available at https://apps.who.int/iris/handle/10665/42682, accessed May 16, 2022.

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*11. Reuter, E., "'Smart Pill' Startup EtectRx Strikes Partnership with Pear Therapeutics," *Med City News*, January 14, 2021, available at https://medcitynews.com/2021/01/smart-pill-startup-etectrx-strikes-partnership-with-pear-therapeutics, accessed May 16, 2022.

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Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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